K062003

510(k) Summary

Submitters information: Lhasa OMS, Inc.
230 Libbey Parkway
Weymouth, MA 02189

SEP 19 2007

Contact Person: Matthew Pike Telephone: 781-340-1010 ext. 12
Fax: 781-340-1637

Date Summary Prepared: April 16, 2007

Device name:
Proprietary name: Neuro Wave 6
Common or usual name: Portable transcutaneous electrical nerve stimulator (TENS)
Classification name: Transcutaneous electrical nerve stimulator, Class II, 21 CFR 882.5890.

Legally marketed device for substantial equivalence comparison:
ES-160, K051020

Description of the device:
The device consists of a battery powered portable instrument with 6 channel outputs.

Weight- 2.6 kg.

Color- Grey

Pulse Shape- Asymmetrical, Biphasic Triangular Wave

Pulse Rate- 1-100 Hz

Pulse Width-

Impedance Value	500 ohms	1000 ohms	2000 ohms	5000 ohms	10000 ohms
Pulse Width	280 µS	240 µS	220 µS	220 µS	220 µS

Output- 80 volts maximum (under 500 ohm test load)

Stimulation time- stimulation time is adjusted by the timer up to 60 minutes.

Device Controls- Clearly indicated are the ON/OFF (Power switch), Frequency Adjuster, Timer, and Output Intensity Knobs.

Power- 6 1.5 volt C batteries

Intended use of the device:
The Neuro Wave 6 is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain. This is a prescription device and should be used under continued medical supervision. The intended use of the ES-160 is identical.

The Neuro Wave 6 cannot be used transcerebrally, in the carotid sinus area or during pregnancy. Patients suspected of having heart disease should consider adequate precautionary measures prior to administration. Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrode is placed across the neck or mouth. This may be enough to close off the airway. Stimulation will inhibit the output of some demand cardiac pacemakers and therefore, is not recommended for patients with this type of pacemaker. Electrical nerve stimulation is a symptomatic treatment, and as such may suppress the progress of pain which would otherwise serve as a protective influence on the outcome of a disease process. The potential for physical and/or psychological dependence upon nerve stimulation as a means of relieving pain has not been determined.

It has been noted that some patients find the sensation of electrical stimulation extremely unpleasant and should probably be excluded from further use of the stimulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lhasa OMS, Inc.
% Mr. Matthew Pike
230 Libbey Parkway
Weymouth, MA 02189

SEP 19 2007

Re: K062003
Trade/Device Name: Neuro Wave 6
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: June 19, 2007
Received: June 21, 2007

Dear Mr. Pike:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

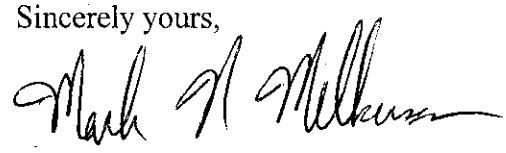
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use

510(k) Number (if known): Device Name: Neuro Wave 6

Indications for Use:
The Neuro Wave 6 is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062003

Prescription Use X AND/OR Over-The-Counter Use _____ (Part 21 CFR 810 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)